

JUN - 1 2007

**510(k) Summary**

**Self-Cath® CS Closed Urinary Catheterization System**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

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The assigned 510(k) number is:

K070939

Contact Person:

Rebeka A. Stoltman  
Manager, Regulatory Affairs  
Coloplast Corp  
1601 West River Road North  
Minneapolis, MN 55411

Telephone: (800) 788-0293, ext. 4997

Facsimile: (612) 287-4138

Email: [usrst@coloplast.com](mailto:usrst@coloplast.com)

Date Prepared:

April 3, 2007

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**Device Name and Classification**

Trade Name: Self-Cath® CS Closed Urinary Catheterization System

Common Name: Intermittent Urethral Urinary Catheter

Classification Name: Urological Catheter and Accessories

Product Code: FCM and KOD

**Legal Manufacturer**

Coloplast A/S  
Holtedam 1  
3050 Humlebaek, Denmark

#### Manufacturing Site (Catheter)

Coloplast Manufacturing US, LLC  
1601 West River Road  
Minneapolis, MN 55411 USA

#### Manufacturing Site (Assembly & Packaging)

Shanghai Amsino Medical Devices Co., Ltd.  
668 Hua Jiang Road  
Shanghai, P.R. China 201803

#### Device Description

The Coloplast Self-Cath<sup>®</sup> CS Closed System catheter (also referred to as “SCCS”) is an extension of the existing Coloplast Self-Cath product line. The device is a modification of the Coloplast (Mentor) Self-Cath Closed System catheter, which was cleared under 510(k) K003873. It is available singly and as part of a kit.

The SCCS is intended to be used to drain urine from the bladder. The SCCS is a catheter and collection bag assembly for inserting a catheter from a closed, sterile bag through an insertion tip into the bladder. It consists of a sterile, pre-lubricated catheter with a pre-lubricated introducer tip on the proximal end, which is designed to reduce patient contact and potential contamination while advancing the catheter into the urethra. The catheter and introducer tip are pre-lubricated with a water-soluble hydrophilic water-based lubricant. The catheter provides a conduit for draining the bladder into the pre-attached urine collection bag.

#### Substantial Equivalence Claim

Coloplast believes the proposed Self-Cath<sup>®</sup> CS Closed System is substantially equivalent in form and function to Coloplast’s Self-Cath Closed System, which was cleared under 510(k) K003873.

#### Indications for Use

The Self-Cath<sup>®</sup> CS Closed System is intended for use in male or female patients needing bladder drainage as determined by their physician. More specifically it is intended for use where drainage of the bladder into a suitable receptacle such as a commode or bedpan is not feasible or practical. The device can be used by either the patient, once appropriate training has taken place, or by a trained health care professional.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Ms. Rebeka Stoltman  
Manager, Regulatory Affairs  
Coloplast Corp.  
1601 West River Road North  
MINNEAPOLIS MN 55411

JUN - 1 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Re: K070939

Trade/Device Name: Self-Cath® CS Closed Urinary Catheterization System  
Regulation Number: 21 CFR §876.5130  
Regulation Name: Urological catheter and accessories  
Regulatory Class: II  
Product Codes: FCM  
Dated: April 30, 2007  
Received: May 4, 2007

Dear Ms. Stoltman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains povidone iodine swabsticks and benzalkonium chloride towelettes, which are subject to regulation as drugs.

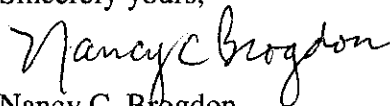
Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857  
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive, Abdominal,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K070939

Device Name: Self-Cath® CS Closed Urinary Catheterization System

Indications for Use:

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Prescription Use X  
(21 CFR 801 Subpart D)

AND / OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K070939